UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:
All Actions

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI

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INTRODUCTION

The Court should deny Plaintiffs' Motion to Exclude Opinions and Testimony of Timothy Ulatowski (ECF No. 756), a regulatory consultant with more than thirty-six years of experience working for the Food and Drug Administration ("FDA").

Mr. Ulatowski offers opinions regarding FDA regulations and the Defendants' compliance with those regulations not just at the time of 510(k) clearance stage, but at times throughout the entire life cycle of the Bair Hugger System. (*See* ECF No. 767, Ulatowski Report (Plaintiffs' Exhibit 2).)[1] His key opinions include: (1) Defendants designed the Bair Hugger Models 505, 750, and 775 in accordance with the governing regulatory and industry standards; (2) the FDA's 510(k) clearance of the Bair Hugger considered, and in part provided reasonable assurance of, safety and effectiveness; (3) the labeling for the Bair Hugger System met regulatory requirements and was consistent with industry standards; (4) Defendants complied with post-market surveillance, investigation, and medical device reporting requirements; and (5) other opinions related to pre-market and post-market regulations, as well as FDA actions and communications.

Mr. Ulatowski also rebuts opinions of Plaintiffs' expert Yadin David. Plaintiffs offer Dr. David to impugn Defendants and the Bair Hugger System based on alleged safety risk, and Dr. David casts many of these opinions in regulatory terms, despite his

[1] Defendants also attach as exhibits the following components of Mr. Ulatowski's report not filed with Plaintiffs' motion to exclude: DX1, curriculum vitae of Timothy Ulatowski (Exhibit A to Ulatowski Report); DX2, Ulatowski Reliance List (Exhibit B to Ulatowski Report); DX3, Ulatowski's Prior Depositions and Testimony (Exhibit C to Ulatowski Report); DX4, September 8, 2017 Supplemental Report of Timothy A. Ulatowski. Cites to "DX" are exhibits to the Declaration of Bridget Ahmann filed concurrently with this opposition.

relative inexperience with the FDA. Mr. Ulatowski's opinions provide needed context to show that Defendants properly addressed the alleged risks with the FDA. As courts have recognized, "[a] lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care" in the pharmaceutical or medical device industries. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009).

Notably, although Plaintiffs cast their Motion as one to exclude Mr. Ulatowski's opinions entirely (*see* ECF No. 756 at 17 (seeking "an order excluding Mr. Ulatowski from testifying in this matter")), Plaintiffs in fact challenge only a small subset of his opinions—primarily, those related to 510(k) clearance. (*See* ECF No. 756 at 3-12.) These arguments fail for many reasons, and, in any event, would not justify excluding Mr. Ulatowski entirely even if they were valid. While Plaintiffs attempt to more broadly challenge Mr. Ulatowski based on "conflict of interest" and lack of qualifications, these arguments have no basis in law or fact, and are not tied to any specific opinions. For all of these reasons, the Court should deny Plaintiffs' Motion in its entirety.

BACKGROUND

I. MR. ULATOWSKI'S BACKGROUND AND QUALIFICATIONS.

Mr. Ulatowski was an employee of the FDA from November 1974 until January 2011, a period of 36 years. (Ulatowski Rpt. at 1.) During that time he held positions of increasing responsibility within the FDA, initially serving in the Center for Drug Evaluation and Research ("CDER"), and eventually moving to the Center for Devices and Radiological Health ("CDRH"), where he held multiple leadership positions over the remainder of his public health career, including as: Director of Investigational Device

Exemption Staff; Branch Chief of General Hospital Devices; Associate Director for General Devices; Director of the Division of Dental, Infection Control and General Hospital Devices; Director of the Office of Compliance; and Senior Advisor for Enforcement. (*See id.* at 1-6.) During his extensive FDA career, Mr. Ulatowski performed, and managed others performing, numerous regulatory processes, including, *inter alia*: premarket approval and 510(k) clearances, the evaluation of manufacturer risk management documents, prioritization and conduct of facility inspections, interpreting and enforcing medical device reporting and other post-market requirements, assessing compliance with labeling regulations, and determining whether emerging health information necessitated a manufacturer field action to prevent patient injury. (*Id*. at 5.)

Mr. Ulatowski has a bachelor's degree in microbiology and a master's degree in physiology with an emphasis in biomedical engineering. (Ulatowski Rpt. at 1.) Since retirement, Mr. Ulatowski has remained current on FDA matters and continues to provide training for national and international regulators. (*Id.* at 6.) He is eminently qualified on regulatory matters and should be permitted to testify.

II. MR. ULATOWSKI'S OPINIONS AND METHODOLOGIES.

Mr. Ulatowski was retained by Defendants to address allegations concerning regulatory issues contained in Plaintiffs' Master Long Form Complaint and Plaintiffs' Motion for Leave to Amend to Add Claim for Punitive Damages, and to respond to the report of Plaintiffs' expert Dr. Yadin David. (Ulatowski Rpt. at 22-23.) His anticipated testimony will provide essential context to assist the jury in understanding how the FDA regulates the medical device industry. Because Plaintiffs contend that Defendants made

obviously wrong or reckless decisions in designing the Bair Hugger System and bringing it to market, the context Mr. Ulatowski can provide will be critical to the jury's assessment of the reasonableness of Defendants' behavior. *See In re Fosamax*, 645 F. Supp. 2d at 191 ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care. . . .").

As reflected in his Report, Mr. Ulatowski will offer numerous regulatory opinions related to Defendants and the Bair Hugger System that include, but go demonstrably beyond, 510(k) clearance matters, including opinions related to device labeling, design history documentation, post-market surveillance, Medical Device Reporting, and post-market FDA inspections and warning letters, among other topics that cumulatively touch on the entire "life cycle" of the Bair Hugger System.[2] (*See* Ulatowski Rpt. at i-ii, 23-113.) Mr. Ulatowski formed these opinions following an extensive review process. (Ulatowski Rpt. at 23.) His methodology included a review of publicly available information and regulatory documents (*id.*), in addition to a substantial record of materials produced in the litigation, including more than 75,000 pages of 3M-produced documents, forty-four deposition transcripts, and more than 250 relevant articles, among other materials. (*Id.* at 23-24; DX2, Ulatowski Reliance List.) This methodology is reliable, is consistent with the methods Mr. Ulatowski ordinarily employs in his profession, and is at least consistent with the methods used by health care companies and

[2] "The 'life cycle' of a device is a term to characterize the period from the point where the product is conceived and the design process begins until the device is no longer on the market." (Ulatowski Rpt. at 14.)

regulatory authorities to evaluate post-approval safety data, risk reduction strategies, and labeling obligations. (Ulatowski Rpt. at 23.)

III. PLAINTIFFS' MOTION TO EXCLUDE MR. ULATOWSKI'S OPINIONS AND TESTIMONY.

Plaintiffs' Motion (ECF No. 756) offers four arguments for excluding Mr. Ulatowski's testimony: (1) that the FDA's 510(k) clearance of the Bair Hugger System is irrelevant and prejudicial (ECF No. 756 at 3-6); (2) that Mr. Ulatowski's opinions as to the 510(k) process are unreliable, based on multiple misguided grounds; (*id.* at 6-12); (3) that Mr. Ulatowski's opinions are biased and prejudicial due to an alleged "conflict of interest" resulting from his regulatory involvement with the Bair Hugger while with the FDA (*id.* at 12-16); and (4) that Mr. Ulatowski is unqualified to opine on "non-regulatory issues" (*id.* at 16-17). For all of the reasons discussed below, the Court should deny Plaintiffs' Motion to Exclude in its entirety.

ARGUMENT

I. THE COURT SHOULD DENY PLAINTIFFS' MOTION AS TO MR. ULATOWSKI'S OPINIONS THAT PLAINTIFFS DO NOT SPECIFICALLY CHALLENGE.

The only opinions by Mr. Ulatowski that Plaintiffs substantively challenge in their Motion are those related to 510(k) clearance. (*See id.* at 3-12.) As noted above, Mr. Ulatowski's opinions go far beyond 510(k). Indeed, while "the 510(k) process is a . . . moment in time based upon documentation at a point in time" (DX5, July 7, 2017 Deposition Transcript of Ulatowski ("Ulatowski Dep.") at 41:9-10), a manufacturer's regulatory responsibilities, and the FDA's regulatory oversight of medical devices neither begin nor end at the moment of 510(k) clearance. Rather, manufacturers are subject to

FDA regulations that govern both pre-submission and post-clearance behavior, and much of Mr. Ulatowski's report addresses the Bair Hugger System in the context of these regulations. Because Plaintiffs do not substantively challenge Mr. Ulatowski's opinions other than those related to 510(k) clearance, the Court should allow Mr. Ulatowski to testify to those opinions.[3]

II. MR. ULATOWSKI'S 510(K) OPINIONS ARE RELEVANT AND RELIABLE.

Plaintiffs devote the majority of their brief to Mr. Ulatowski's 510(k) opinions. Among other things, Mr. Ulatowski opines that safety and effectiveness factored into FDA's review of every Bair Hugger 510(k); that the Bair Hugger Models 505, 750 and 775 met all premarket requirements and that FDA's orders clearing these devices provided, in part, reasonable assurances of safety and effectiveness; and that FDA's clearance of later Bair Hugger 510(k)s reconfirmed the safety and effectiveness of the device. (*See* Ulatowski Rpt. at 25-41.) Plaintiffs move to exclude these opinions, contending: (1) they are irrelevant and prejudicial, and (2) they are not the product of reliable methodology. (ECF No. 756 at 3-12). Plaintiffs are wrong on both grounds.

A. Mr. Ulatowski's Opinions Regarding 510(k) Clearance Are Relevant and Far More Probative than Prejudicial.

Mr. Ulatowski's proposed testimony about the 510(k) clearance process, both generally and with respect to the Bair Hugger, is highly relevant to the Plaintiffs' claims and Defendants' defenses. Plaintiffs contend that Defendants made obviously wrong and

[3] While Plaintiffs vaguely purport to challenge Mr. Ulatowski's other opinions on grounds that he is "biased" and "unqualified," those arguments fail categorically as discussed below in Sections III and IV.

reckless decisions in designing the Bair Hugger System and bringing it to market. Mr. Ulatowski's 510(k) testimony will counter this claim by educating the jury on the regulatory framework that governs the clearance of new devices, the regulatory requirements manufacturers must satisfy to gain 510(k) clearance, and the considerations the FDA factors into its review of 510(k) applications. If successful, Plaintiffs' attempts to exclude testimony regarding the 510(k) process would result in the jury evaluating the Bair Hugger, as well as the Defendants' behavior in development and marketing the Bair Hugger, in a vacuum—as if Defendants manufactured and distributed the product with no government involvement or oversight at all. Plaintiffs would further have their experts criticize the Defendants' behavior in designing and marketing the product, again without reference to the very regulatory scheme that guided that behavior. A trial that ignores this federal context would be unfairly prejudicial to Defendants and would mislead the jury. *See In re Fosamax*, 645 F. Supp. 2d at 191 ("A lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care. . . .").[4]

Mr. Ulatowski's opinions and testimony are especially critical to rebut Plaintiffs' proposed regulatory expert, Yadin David. For example:

[4] In contrast to regulatory opinions that a defendant "violated the law with respect to the FDA" or that a product is "adulterated" or "misbranded" for purposes of the Food, Drug & Cosmetic Act, expert testimony regarding FDA regulations and a manufacturer's compliance therewith—so long as it is offered by a qualified expert and based upon reliable methodologies—is often admitted in products liability actions. *See Kruszka v. Novartis Pharms. Corp.*, 28 F. Supp. 3d 920, 934 (D. Minn. 2014) (excluding regulatory expert opinions that defendant "violated the law with respect to the FDA," but allowing testimony "on the FDA regulatory process and regulations and on [defendant's] compliance"); *In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, No. 12-C-6279, 2015 WL 5145546, at *18 (N.D. Ill. Aug. 31, 2015); *see also Wyeth v. Levine*, 555 U.S. 555, 570 (2009) ("[B]ecause the statute contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a drug is misbranded is not conclusive").

- Dr. David criticizes the Defendants for bringing the Bair Hugger System to market without first performing a "risk assessment" in the form he purports to have performed in his report. (ECF No. 316, David Rpt., at 5-7, 44.) Mr. Ulatowski, in rebuttal, clarifies that Defendants *did perform* a risk assessment that met regulatory and industry standards, and that Dr. David's "hazard analysis" is not in the "form or manner of an industry standard medical device hazard analysis. . . ." (Ulatowski Rpt. at 51, 86; Ulatowski Dep. at 258:4-16; 391:6-20.)

- Dr. David alleges that changes to the Bair Hugger system's filter media meant that "information about the device which has been given to the FDA over the years has not been accurate or complete." (ECF No. 316, David Rpt. at 21-24, 44.) Mr. Ulatowski's opinion provides necessary context showing the two filter media were substantially equivalent and that Defendants' regulatory submissions were therefore appropriate. (Ulatowski Rpt. at 42-48; Ulatowski Dep. at 336:21-337:4, 338:19-339:9.)

With 36 years of experience working for FDA and with the very regulatory framework discussed in his report, Mr. Ulatowski's testimony on 510(k) clearance and other matters provides necessary context for the jury to evaluate Dr. David's less informed testimony.

B. Plaintiffs' Cited Case Law Does Not Establish Otherwise.

In an effort to challenge Mr. Ulatowski's 510(k) opinions, Plaintiffs rely upon: (1) inapposite Supreme Court precedent relating to issues of preemption (not admissibility); (2) a selection of recent cases out of the Fourth Circuit that are non-binding, and that depart from multiple decisions within the District of Minnesota; and (3) past cases in which Mr. Ulatowski's 510(k) testimony has been excluded, while ignoring cases in which his 510(k) opinions have been allowed. The Court should reject these arguments and allow Mr. Ulatowski to testify to the 510(k) clearance process.

Plaintiffs err in relying upon the Supreme Court decisions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), to argue that Mr. Ulatowski's testimony on that subject is "not relevant to a determination of the

safety or effectiveness of a device in a tort action." (ECF No. 756 at 3.) These two cases focus on the issue of federal preemption of state-law personal injury claims, and have nothing to do with the relevance of evidence concerning the 510(k) process in a product liability case. See *Lohr*, 518 U.S. at 474 ("The question presented is whether that statute pre-empts a state common-law negligence action against the manufacturer of an allegedly defective medical device."); *Riegel*, 552 U.S. at 315 ("We consider whether the preemption clause enacted in the Medical Device Amendments of 1976…bars common-law claims…"). Whether a federal regulation forecloses a state-law cause of action as a matter of law is a much different question than the admissibility of evidence concerning the extent to which the 510(k) process evaluates safety and effectiveness. For example, Mr. Ulatowski does not suggest that 510(k) clearance, or FDA's evaluation of safety and effectiveness, is dispositive of whether the Bair Hugger system is defective or that Defendants met the industry standard of care. Rather, his testimony will simply inform the jury about the nature of FDA's 510(k) review, provide critical context regarding the regulatory environment in which the Defendants acted, and rebut the regulatory opinions of Dr. David on the same issues. (ECF No. 316, David Rpt., at 17-18.)

Courts in this district, in cases decided after *Lohr* and *Riegel*, have found the 510(k) process to be relevant in cases involving negligence claims. For example, in *Huggins v. Stryker Corp.*, the Court reasoned:

> Huggins' evidence regarding Stryker's interactions with the FDA [specifically multiple unsuccessful attempts to secure 510(k) clearance] and subsequent marketing is relevant as part of a body of evidence, including the available scientific literature and the feasibility of safety testing, that sheds light on what risks a jury could reasonably find that Stryker should have discovered. The manufacturer is held accountable as an expert in its

> field only for those dangers of which it has knowledge or those which it could discover through the exercise of reasonable care. What constitutes "reasonable care" depends on the surrounding circumstances. Here, those circumstances include Stryker's interactions with the FDA and its marketing strategies.

932 F. Supp. 2d 972, 990 (D. Minn. 2013) (quotations and citations omitted). Case law makes clear that "evidence of a regulatory or statutory scheme and its alleged violation can constitute evidence of negligence." *Lillebo v. Zimmer, Inc.*, No. 03-2919, 2005 WL 388598, at *4-5 (D. Minn. Feb. 16, 2005); *see also Morey v. Mentor Worldwide LLC*, No. 4:11-CV-5065 CDL, 2013 WL 5797856, at *2 (M.D. Ga. Oct. 28, 2013) ("As the Court ruled during the trial, the fact that the FDA took no adverse action regarding ObTape between the FDA clearance date and the date of Morey's implant could be relevant on the question whether Mentor was negligent with regard to ObTape as of the date of Morey's implant."). Plaintiffs in this case assert claims based upon both negligence and design defect (*see* ECF No. 97, Master Long Form Compl. ¶¶ 69-100), and thus Mr. Ulatowski's testimony about the regulatory process is both relevant and admissible.

Furthermore, to the extent *Lohr* imparts any opinion as to the relevance of the 510(k) process to the issue of product safety, it is important to recognize that, in 1990, Congress altered the statutory definition of 510(k) "substantial equivalence" to require consideration of safety and effectiveness at the clearance stage. *See* Safe Medical Devices Act of 1990, Pub. L. No. 101-629, at 4515.[5] This change took place after the

[5] The Medical Device Amendments of 1976 required only that a device cleared through 510(k) be "substantially equivalent to another device within such type," without additional guidance. See Medical Devices Amendments of 1976, Pub. L. No. 94-295, at 544-45. In contrast, the Safe Medical Devices Act of 1990 required that a manufacturer certify that it "conducted a reasonable search of all information known or otherwise

product at issue in *Lohr* received clearance—1982, *see Lohr*, 518 U.S. at 480—and prior to the clearance of the Bair Hugger models at issue in this case. *See* DX6, June 17, 1996 Bair Hugger Model 505 Clearance Letter; DX7, September 6, 2000 Bair Hugger Model 750 Clearance Letter. *Riegel*, meanwhile, addressed a device subject to premarket approval, and therefore did not analyze this change in the law. 552 U.S. at 322-23.

The Supreme Court also decided both *Lohr* and *Riegel* cases well before the FDA issued various guidance documents clarifying that the 510(k) process does, in fact, evaluate safety and effectiveness. For example, FDA has stated that "[a] 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is *at least as safe and effective as the predicate*" (emphasis added).[6] FDA has also explicitly stated that while the 510(k) standard is comparative and the Premarket Approval standard relies on an independent demonstration of safety and effectiveness, "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."[7]

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available to the manufacturer respecting such other device and has included in the report under section 510(k) a summary of and a citation to *all adverse safety and effectiveness data* respecting such other device and respecting the device for which the 510(k) report is being made." Pub. L. No. 101-629, at 4515 (emphasis added).

[6] DX8, Premarket Notification (510k), U.S. FOOD & DRUG ADMIN. (last updated August 28, 2017) (accessed Sept. 25, 2017), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm.

[7] DX9, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], Guidance for Industry and Food and Drug Administration Staff*, at 6, U.S. FOOD AND DRUG ADMIN. July 28, 2014, available at http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.pdf.

According to FDA, the substantial equivalence determination is "grounded in safety and effectiveness" and "depends upon the safety and effectiveness of the new device for the new indications relative to the safety and effectiveness of the predicate device."[8] Further, in evaluating a 510(k) notification, "FDA generally evaluates differences between the new device and the predicate device to determine their effect on safety and effectiveness."[9] Mr. Ulatowski's opinions are consistent with this guidance.

The handful of cases Plaintiffs cite that agree with their argument are unhelpful in this case. The Fourth Circuit opinion that Plaintiffs quote extensively was limited in scope, as it applied only to strict liability claims and did not assess relevance vis-à-vis negligence. *See In re C.R. Bard, Inc.*, MDL. No. 2187, *Pelvic Repair System Products Liability Litigation*, 810 F.3d 913, 918 (4th Cir. 2016); *see also Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 754 (S.D. W. Va. 2014). Moreover, *Bellew v. Ethicon, Inc.*, 2014 WL 6674424, at *8 (S.D. W. Va. 2014), like *Lohr* and *Riegel*, is a decision limited to the issue of preemption and does not address relevance.

In re NexGen provides an example of a case in which the Court regulatory testimony was irrelevant to the ***defect*** component of the claim. *In re Zimmer NexGen Knee Implant Prod. Liab. Litig.*, No. 11 C 5468, 2015 WL 5145546, at *18 (N.D. Ill. Aug. 31, 2015). Notably, that exclusion did not apply to testimony about the conduct of the parties, an assessment which the *NexGen* court limited to punitive damages, but which is also relevant to Plaintiffs' negligence claim here. As Defendants have already shown, the broad exclusion in *NexGen* is contrary to the prior decisions in this District.

[8] *Id.* at 17.
[9] *Id.* at 7.

Finally, although Plaintiffs argue that Mr. Ulatowski's testimony on 510(k) clearances has been excluded in two other matters, including *NexGen* (*see* ECF No. 756 at 4-6), Plaintiffs ignore the cases in which such testimony has been challenged, but upheld. *See, e.g.*, *Retractable Technologies, Inc. v. Becton, Dickinson and Co.*, No. 2:08–CV–16–LED–RSP, 2013 WL 4574258, at *2 (E.D. Tex. Aug. 27, 2013) (rejecting plaintiff's argument that Mr. Ulatowski's 510(k) opinions were irrelevant and prejudicial); *Retractable Technologies, Inc. v. Becton, Dickinson and Co.*, No. 2:08–CV–16–LED–RSP, 2013 WL 4101810, at *2 (E.D. Tex. Aug. 12, 2013) (concluding that "the safety of [a product] is an issue in the case, that the FDA [510(k) clearance] is relevant to that issue, and that the limitations of the process can easily be explained to the jury"); *see also Braun, et al. v. Medtronic Sofamor Danek*, No. 2:10-cv-01283-RJS, ECF No. 535 (D. Utah Feb. 5., 2014) (DX10) (precluding Mr. Ulatowski from "speculat[ing] on what FDA would have done" and "instruct[ing] the jury on the law," but otherwise allowing Mr. Ulatowski's testimony to go forward). As noted above, courts within this District have ruled in a manner consistent with *Retractable Technologies*, and have allowed experts to testify on the 510(k) process. *See, e.g.*, *Huggins*, 932 F. Supp. 2d at 990; *see also Lillebo*, 2005 WL 388598, at *4 ("[E]vidence of a regulatory or statutory scheme and its alleged violation can constitute evidence of negligence."). This Court should do the same.[10]

[10] Even if the Court concludes that Mr. Ulatowski's 510(k) opinions are for any reason inadmissible, this should not bar Mr. Ulatowski's testimony entirely. As noted above, Mr. Ulatowski's opinions extend far beyond 510(k) clearance. The relevance and reliability of Mr. Ulatowski's 510(k) opinions—which relate to a moment in time—have no bearing on the admissibility of his other opinions.

C. Mr. Ulatowski's Methodology is Reliable.

In forming his opinion, Mr. Ulatowski reviewed a substantial record of documentation ranging from the Bair Hugger System's design history file, to regulatory communications, to documents related to ongoing device assessment. (*See, e.g.*, Ulatowski Rpt. at 41-42, 50-51, 81-82; *see also* Ulatowski Reliance List.) Such a methodology is "consistently used by health care companies and regulatory authorities to address and evaluate post-approval safety data, risk reduction strategies and labeling obligations." (Ulatowski Rpt. at 23.)

Nevertheless, Plaintiffs contend Mr. Ulatowski's methodology in forming his 510(k) opinions was unreliable, based on four grounds. Plaintiffs' arguments include: (1) that Mr. Ulatowski was not provided with the FDA's "decision-making documentation relating to the Bair Hugger 500 Series;" (2) that he was unable at deposition to provide the name of the scientific study that he relied upon in concluding that "valid scientific evidence" existed in support of the use of the Bair Hugger in operating rooms at the time of 510(k) clearances; (3) that he employed an incorrect regulatory standard in forming one of his opinions on warnings; and (4) that his opinions regarding the purpose of 510(k) review conflict with the findings of a 2011 report by the Institute of Medicine ("IOM"). As discussed further below, many of these arguments misconstrue Mr. Ulatowski's sworn testimony and rely upon half-truths; and none of them support exclusion.

1. Mr. Ulatowski received and appropriately addressed the FDA's decision-making documentation for the Bair Hugger 500 series.

Plaintiffs' primary methodological criticism is their contention that Mr. Ulatowski was not provided the FDA decision-making documentation produced in this case that related to Bair Hugger Model 500. (ECF No. 756 at 6-10.) This decision-making documentation includes a checklist filled out by an FDA reviewer at the time he reviewed the 510(k) submission for the Bair Hugger Model 500. (Plaintiffs' Exhibit 3.) The checklist shows some of the determinations made by the reviewer on the path to ultimately concluding that the Bair Hugger models, which for the first time were being cleared for use in the operating room, were "substantially equivalent" to predicate devices. *Id.* Plaintiffs suggest that Defendants improperly withheld this documentation from Mr. Ulatowski, and that it contradicts his 510(k) opinions in relation to the Model 500. The Court should reject these arguments.

As an initial matter, Plaintiffs' contention that Mr. Ulatowski was not provided this documentation is untrue. In fact, Mr. Ulatowski received the documents Plaintiffs cite during his work on a Bair Hugger case prior to MDL consolidation (*Walton v. 3M*, No. 4:13-cv-01164 (S.D. Tex.)). Plaintiffs should be aware of this fact because Mr. Ulatowski listed this document by its Walton Bates number (3M00058118) in his Reliance List for both his Walton report (*see* ECF No. 768, Exhibit 6) and his MDL Report (*see* DX 2 at page 3 of 31 (listed as "Additional 510(k) documents")), and because, as soon as Mr. Ulatowski realized the error in his deposition testimony, he corrected it in his deposition errata sheet. (*See* DX11, Ulatowski Errata Sheet (correcting pp. 88 and 96).) While Mr. Ulatowski did not recall this particular document at the time

of his deposition, and did testify that he did not recall seeing it before, Plaintiffs offer no authority for the proposition that an expert's failure to recall in deposition a single document among tens of thousands of pages reviewed provides a basis for exclusion. *See In re Viagra Prod. Liab. Litig.*, 572 F. Supp. 2d 1071, 1089 (D. Minn. 2008) (rejecting *Daubert* argument unsupported by legal authority).

Second, Plaintiffs' argument that the 510(k) decision-making documents contradict Mr. Ulatowski's opinions is misguided.[11] During Mr. Ulatowski's deposition, Plaintiffs' counsel asked Mr. Ulatowski the same question repeatedly in order to simplify Mr. Ulatowski's nuanced response into a simple yes or no answer. (Ulatowski Dep. at 135:19-136:1; 139:17-22; 144:11-20; 155:1-8; 161:3-18). The recurring question was whether the proposed use of the Bair Hugger 500 Series in operating rooms constituted a change in the product's "Indications for Use." This question required a nuanced answer because, as Mr. Ulatowski explained, indications for use are more easily applied to drugs than devices. (Ulatowski Dep. at 82:25-83:5; 154:6-19).

Nonetheless, Mr. Ulatowski responded multiple times that a reviewer could reasonably view deployment in an operating room as either a change in the Bair Hugger's indications for use or as no change. (Ulatowski Dep. at 135:19-136:1 (stating "it may be [a change] relative to indications for use"), 147:2-3 ("It may not be particularly highly significant to the FDA, the evolution into the OR.") Mr. Ulatowski himself evaluated

[11] Because Plaintiffs incorrectly allege an inconsistency, Defendants seek to correct the record. However, Plaintiffs contradict themselves in terms of the meaning of the alleged inconsistency. Somehow, Plaintiffs intend to use the alleged inconsistency to both render Mr. Ulatowski's opinions unreliable and prove that the FDA's approach to the 510(k) clearance was erroneous, not Mr. Ulatowski's. (ECF No. 756 at 8.)

this as a change to the "environment of use," which he viewed as possibly insignificant in the FDA's eyes. (*Id.* at 145:21-147:3.) He thereafter stated that, regardless of whether the FDA reviewer found a change to the device's indications for use, there "would have been an assessment to one degree or another of the differences, including differences and their impact on safety and effectiveness." (*Id.* at 163:13-16.)

When faced with the FDA reviewer's decision-making documentation, showing that the reviewer found no change in the indications for use with the Model 500, Mr. Ulatowski's story remained consistent: this was a reasonable position for the reviewer to take. (*Id.* at 167:14-20, 168:6-12.) Thus, there is no inconsistency between Mr. Ulatowski's nuanced assessment of the 510(k) review process and the actual review applied by the FDA.

Finally, Plaintiffs attempt to use the decision-making document to make the case that the FDA made no safety and effectiveness determination with regard to the Model 500 510(k) submission. This, however, is contradicted by the very document that Plaintiffs have conveniently cropped into their brief. The entirety of the document shows that the reviewer considered the question "Could the new characteristics [of the device] affect safety and effectiveness?" (ECF No. 769, Model 500 510(k) Decision-making Documentation (Plaintiffs' Exhibit 3), at 3MBH00047439.) The reviewer answered this question "no." (*Id.*)

2. Mr. Ulatowski's inability at deposition to recall the name of one article he relied upon does not warrant exclusion.

Plaintiffs next briefly argue, without legal citation, that Mr. Ulatowski's 510(k) opinions should be excluded because he was unable at deposition to provide the name of

the study he had identified as providing "valid scientific evidence of the Bair Hugger's use in operating rooms." (ECF No. 756, at 10-11.) Mr. Ulatowski testified that he knew the article existed and believed that it was included within a letter that Defendants had submitted to the FDA, but that he could not recall the name of the study off the top of his head. (Ulatowski Dep. at 128:22-134:22.) Mr. Ulatowski asked for an opportunity to consult the letter to refresh his memory but counsel repeatedly refused to provide a copy. (Ulatowski Dep. at 129:23-130:5, 130:14-22, 133:4-17.) Mr. Ulatowski ultimately identified the article he had in mind as part of his errata sheet. (DX11, Ulatowski Errata Sheet (correcting p. 134).)[12]

A deposition is not a memory game in which a player is eliminated because he is unable to recall a specific detail. *See, e.g.*, *United States v. Johnson*, 860 F.3d 1133, 1140 (8th Cir. 2017) (admitting expert despite her inability to recall details about a study); *In re Levaquin Prod. Liab. Litig.*, No. MDL 08-1943 JRT, 2010 WL 8399942, at *9-10 (D. Minn. Nov. 4, 2010) (rejecting Daubert motion based, in part, on expert's "inability to recall the order in which he reviewed each file" in the case and inviting Plaintiffs to "use cross-examination to challenge" the expert on such issues). In this case, Plaintiffs may attempt to cross-examine Mr. Ulatowski on the issue of forgetting the details of a specific study while at deposition, but it is no basis for exclusion.[13]

[12] The study is entitled "Comparison of Intraoperative Warming Devices" and is attached as DX12 for the court's review.

[13] Plaintiffs' attempt to challenge the use of the Bair Hugger System in operating rooms is especially hollow in light of the FDA's recent findings and comments to health care providers that the use of "thermoregulation devices during surgery, including forced air thermoregulating systems [of which the Bair Hugger system is by far the most commonly used], have been demonstrated to result in less bleeding, faster recovery times, and

3. Mr. Ulatowski's warning opinion is not inconsistent with Bluebook Guidance.

Plaintiffs also take issue with Mr. Ulatowski's opinion that the addition of a warning of infection risk with the Bair Hugger System was not justified due, in part, to "the lack of a direct causal relationship of infections to forced air warming." (ECF No. 756, at 11.)[14] Plaintiffs claim that this statement is contrary to the FDA Bluebook's guidance that "a causal relationship need not have been proved" for a product to merit a warning. However, there is no contradiction between the two statements: Mr. Ulatowski said that the lack of a causal relationship was *one of several factors* that led to his conclusion. (Ulatowski Rpt. at 74.) A lack of a causal relationship can inform a manufacturer's decision on a warning, even if in some cases it is not an independently sufficient reason not to warn. Furthermore, this purported contradiction is no basis for exclusion. Plaintiffs simply disagree with Mr. Ulatowski's reasoning rather than the method underlying it, and such disagreement does not render an opinion inadmissible. *See Hill v. Sw. Energy Co.*, 858 F.3d 481, 486 (8th Cir. 2017).[15]

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decreased risk of infection for patients." DX13, FDA Safety Alert, "Forced Air Thermal Regulating Systems: Healthcare Provider Letter – Information About Use" (Aug. 30, 2017).

[14] Notably, Mr. Ulatowski was simply repeating the words of Dr. David in acknowledging the lack of a direct causal relationship. (Ulatowski Rpt. at 74.) Mr. Ulatowski was not independently opining to such a relationship.

[15] Mr. Ulatowski's opinion regarding the lack of justification for an infection risk warning is further corroborated by the FDA's comments in its August 30, 2017, letter to healthcare professionals. *See* DX13 (noting that the use of "thermoregulation devices during surgery, including forced air thermoregulating systems, ha[s] been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.").

4. Mr. Ulatowski's opinion accurately describes the purpose of the 510(k) process.

Plaintiffs dispute the statement in Mr. Ulatowski's report that "there is reasonable assurance that a Class II device is safe and effective when it meets all general controls and any special controls." Plaintiffs allege that this statement contradicts conclusions from a 2011 Institute on Medicine report, and therefore should be excluded as unreliable. (ECF No. 756, at 11-12.)

Mr. Ulatowski's statement is a quote directly from 21 U.S.C. § 360(c), not a random, unsupported statement. (*See* Ulatowski Rpt., at 35.) Furthermore, Plaintiffs present no challenge to Mr. Ulatowski's 36 years at the FDA, which serve as additional foundation for this statement. Plaintiffs' preferred report can be used as a basis for cross-examination of Mr. Ulatowski at trial, but it need not be taken as the gospel truth. It certainly is no basis for exclusion. *See Hill*, 858 F.3d at 486 (disagreement with an expert's conclusions is not a basis to exclude).

For all of the above reasons, Plaintiffs' methodological challenges fail, and the Court should deny Plaintiffs' Motion to Exclude as to Mr. Ulatowski's 510(k) opinions.

III. MR. ULATOWSKI HAS NO CONFLICT OF INTEREST THAT PRECLUDES HIS TESTIMONY.

Plaintiffs next assert that Mr. Ulatowski's past experience as Director of CDRH, which involved minimal contact with the Bair Hugger System, presents a conflict of interest that merits exclusion. (ECF No. 756, at 12-16.) Plaintiffs contend that this "conflict" could render Mr. Ulatowski "less likely to state that the [Bair Hugger System] is anything but safe in this litigation." *Id.* at 14.

Contrary to Plaintiffs' suggestion, no conflict or bias exists. Plaintiffs cite no authority that recognizes the type of conflict plaintiffs purport to identify. Neither FDA regulations nor any other component of federal law imposes obligations, ethical or otherwise, that are contravened by Mr. Ulatowski's engagement or testimony in this matter. Indeed, Mr. Ulatowski has consulted with the FDA's Ethics Office on multiple occasions in the past, and has been informed that he can engage in regulatory consulting in the context of litigation in any matter as long as he refrains from testifying to "anything [he] heard or discussions at FDA," and does not rely upon "any documentation that [he] may have from FDA." (Ulatowski Dep. at 34:20-35:7, 36:1-15.) Plaintiffs provide no indication that Mr. Ulatowski violated any of the parameters prescribed by the FDA Ethics Office. The fact that, in his time as a regulator, Mr. Ulatowski had limited contact with a particular product does not render him too biased or otherwise disqualified to present a reliable discussion of that product's regulatory history. Neither case law nor ethical standards nor logic provide any basis for a finding of a conflict of interest.

Furthermore, none of the documents to which Plaintiffs cite establish any alleged bias or conflict of interest:

- **1998 Clearance of Blood Fluid Warmer.** Mr. Ulatowski's signature on an April 30, 1998 510(k) clearance letter for a blood fluid warmer (Plaintiffs' Exhibit 4) is irrelevant to any of the issues on which Mr. Ulatowski opines in this litigation. At the time it was granted, Mr. Ulatowski was working in the Office of Device Evaluation's Division of Dental, Anesthesiology, General Hospital, and Infection Control Devices. *See* DX1. This Division regulates products like surgical drapes and disinfectants (Ulatowski Rpt. at 3), and did not oversee the clearance of the Bair Hugger hardware at issue in this case. (*See, e.g.*, *See* DX6, June 17, 1996 Bair Hugger Model 505 Clearance Letter; DX7, September 6, 2000 Bair Hugger Model 750 Clearance Letter.) Mr. Ulatowski did not review or clear any products relevant to this litigation, as Plaintiffs suggest. (Ulatowski Dep. at 9:2-10.)

- **2010 Correspondence Regarding Augustine MDR.** Mr. Ulatowski did not even receive the August 16, 2010 letter submitted as Plaintiffs' Exhibit 5. In July 2010, Mr. Ulatowski had assumed a temporary position as Senior Advisor for Enforcement, and another individual assumed his duties as Director of Compliance. (Ulatowski Dep. at 227:1-23.) As a result, this letter would have been directed to his replacement, not to Mr. Ulatowski. (Ulatowski Dep. at 228:8-15.)

- **2010 Warning Letter to Arizant.** Although Mr. Ulatowski did sign a 2010 warning letter to Arizant, this letter concerned the issue of reporting of burn injuries during the use of the Bair Hugger system, and was unrelated to any alleged risk of infection. (Ulatowski Rpt. at 75.) Accordingly, there is nothing about this letter that precludes Mr. Ulatowski from engaging or testifying in this litigation. (Ulatowski Dep. at 36:16-21.)

Despite Plaintiffs' professed concerns, there is also no risk of jury confusion. Defendants have no intention of introducing the above-referenced documents at trial, nor do they intend to suggest to the jury that Mr. Ulatowski speaks for the FDA.

Mr. Ulatowski's testimony demonstrates that he had no involvement with the Bair Hugger System while at FDA that is in any way material to this litigation. And even if he had, Plaintiffs provide no case law or other authority establishing that such involvement would give rise to a "conflict of interest" or otherwise warrant exclusion of his testimony. Plaintiffs' arguments at most go to the weight, not the admissibility, of Mr. Ulatowski's opinions, and are points for cross-examination, not a *Daubert* motion to exclude. *See DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000) ("Determining the credibility of a witness is the jury's province, whether the witness is lay or expert."); *Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 830 (D. Minn. 2011) (holding that an argument of expert bias applied to "the weight of the testimony, not its admissibility"). For all of these reasons, the Court should deny Plaintiffs' Motion as to any alleged "conflict" of Mr. Ulatowski.

IV. THE COURT SHOULD DENY PLAINTIFFS' MOTION AS TO MR. ULATOWSKI'S "NON-REGULATORY" OPINIONS.

Plaintiffs' final argument seeks exclusion of "any potential testimony regarding topics in which Mr. Ulatowski admits to a lack of expertise." (ECF No. 756, at 16.) Although Plaintiffs seek to broadly categorize these as "non-regulatory opinions," the only opinion that they specifically challenge is that of medical causation—an issue Defendants acknowledge Mr. Ulatowski does not intend to address. Although Plaintiffs contend Mr. Ulatowski is unqualified to offer opinions in a variety of other subject matters, Plaintiffs do not identify any actual opinions in Mr. Ulatowski's report or deposition that they seek to exclude based on those lack of qualifications, and accordingly, neither the Court nor Defendants have any basis to judge whether Mr. Ulatowski is competent to opine on those matters. The Court should therefore deny Plaintiffs' Motion as to unspecified "non-regulatory opinions." *See United States v. Ali*, No. CRIM. 10-187, 2011 WL 4583826, at *4 (D. Minn. Sept. 30, 2011) (denying general request to limit expert's testimony, reasoning that "concerns regarding the scope of [the expert's] testimony can be addressed through objections and on cross-examination"); *see also Fisher v. Ciba Specialty Chemicals Corp.*, No. 03-0566-WS-B, 2007 WL 2302470, at *11, n.20 (S.D. Ala. Aug. 8, 2007) (denying motion to strike expert affidavit because defendants' motion did "not recite an objection with sufficient specificity to enable the Court to address it, and the Court will not refine defendants' objection for them").

V. MR. ULATOWSKI'S OPINIONS AND TESTIMONY ARE ALSO ADMISSIBLE UNDER MINNESOTA LAW.

Minn. R. Evid. 702 states that a qualified expert's opinions and testimony are admissible if it has both: (1) foundational reliability, and (2) general acceptance in the relevant scientific community. *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). *See also McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. App. 2004) (affirming the district court's determination that plaintiff's expert's general causation theory is not generally accepted). As detailed above, Mr. Ulatowski applies the methodology that he and others at the FDA applied to the specific regulatory issues present in this case. The general acceptance of these principles by the relevant scientific community is made clear by Mr. Ulatowski's successful application of this methodology over the course of his 36-year career. His opinions and testimony are thus admissible.

CONCLUSION

For all of the reasons discussed above, the Court should deny Plaintiffs' Motion to Exclude Opinions and Testimony of Timothy Ulatowski in its entirety.

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Respectfully submitted,

s/Bridget M. Ahmann

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